K000724

MAR 22 2001

11.0 510(k) Summary

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1. The submitter of this premarket notification is: Medica s.r.l. Via Degli Artigiani 4/a 41036 Medolla (Modena) Italy, through its consultant, EXPERTech Associates, Inc., 100 Main Street, Suite 120 Concord, MA 01742 Attn: James Delaney

This summary was prepared on February 16, 2000.

2. The name of this device is the Medica HP300 Hemofiltration Pump with disposable tubing set. The common name is Blood Pump for Continuous Renal Replacement. Classification name is as follows:

| Regulation Number | Classification Name |
|---|---|
| 878.5860 | High Permeability Hemodialysis system |

3. The Medica HP300 with disposable tubing set is substantially equivalent to the Baxter Blood Monitor Model bm11, marketed pursuant to K911315/A.

4. The Medica HP300 Hemofiltration Pump and disposable is a microprocessor based device that when coupled with a tubing set and appropriate accessories can be used for continuous renal replacement therapies.

5. The device has the same intended use as the legally marketed predicate device.

6. The technological characteristics are the same or similar to those found with the predicate device.

7. Verification, validation, and testing activities were conducted to establish the performance and reliability characteristics of the new device with respect to the predicate. Testing involved electrical safety tests, failure simulations, and software tests.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 2 2001

Medica S.r.l.
c/o Mr. James Delaney
EXPERTech Associates, Inc.
100 Main Street
Suite 120
CONCORD MA 01742

Re: K000724
Medica HP300 Hemofiltration Pump with
Disposable Tubing Set
Dated: December 21, 2000
Received: December 22, 2000
Regulatory Class: II
21 CFR §876.5860/Procode: 78 KDI

Dear Mr. Delaney:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

# Indications for Use Statement

510(k) Number (if known) K000724

Device Name: The Medica HP300 Hemofiltration Pump with Disposable Tubing Set

Indications for Use: The Medica HP300 Hemofiltration Pump with Disposable Tubing Set is intended for continuous renal replacement therapies in adult patients with acute renal failure, using either single or double needle treatment, in the following applications: Continuous Venous-Venous Hemofiltration (CVVH), and Continuous Venous-Venous Hemodiafiltration (CVVHD).

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K000724